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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/212,556	12/16/1998	SHINICHI KURAKATA	980689/HG	8315

7590 12/05/2001

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EXAMINER

OWENS JR, HOWARD V

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 12/05/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/212,556

Applicant(s)

KURAKATA ET AL.

Examiner

Howard V Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 15-28 and 42-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 29-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15 & 16
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Response to Arguments

The following is in response to the amendment filed 9/18/01:

An action on the merits of claims 1-14 and 29-41 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

Applicant's arguments regarding the cancellation of claims 15-28 and 42-67 has been considered; however, the finality of the election/restriction is maintained. Claims 42-67 do not contain generic or linking claims and are separate/distinct from claims 1-14 and 29-41 of the previously elected Group I. Pursuant to 37 CFR 1.142(b) these claims should be canceled considering that assuming arguendo that claims 1-14 and 29-41 were to be allowed, Group II would still require a separate search from that of Group I.

In Claims 15-28 and 42-67 pursuant to 37 CFR 1.142(b) applicant should take the appropriate action and amend the claims to reflect only the elected species I, since the non-elected species clearly constitute distinct structures from those of species I, varying from tricyclic sulfaminos to biphenyl ethers, wherein although the method of treatment is the same, the divergent structures could not render the claims of species 1 obvious.

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35 U.S.C. 103

The rejection of claims 1-14 and 29-41 under 35 U.S.C. 103(a) as being unpatentable over Kimura et al., EP 0799823 A1 and Strelkov et al., American Journal of Physiology, vol. 257, C261-C269 is maintained for the reasons of record.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In the instant case, the motivation to use the instant compounds to treat cachexia or side effects of tumor related disorders was provided from the teachings of Kimura and Strelkov et al.

Kimura et al., teach the analogous diphenylpyrrole compounds of species 1 of the instant invention. Kimura et al. teach that these compounds as cyclooxygenase-2 inhibitors inhibit prostaglandins. Kimura et al. however does not teach the usefulness of these compounds to treat cachexia or disorders resulting from tumors.

Strelkov et al. teach that the inhibition of prostaglandin production counters tumor related cachexia or muscle wasting and other deleterious side effects of tumors (p. C267), which adequately bridges the nexus between the differences in the prior art and the invention as claimed.

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Applicant further argues that Strelkov does not teach that inhibition of prostaglandin production, but merely presents hypotheses and possible pathways. Applicant should note that the prior art need not explicitly teach applicant's invention, only provide a reasonable expectation of success. As such, the data presented by Strelkov in summation on p. C267 as well as tables 1-4 demonstrating weight gain in the presence of a prostaglandin inhibitor clearly show a nexus between the inhibition of prostaglandins and a decrease in muscle wasting or cachexia.

Applicant's arguments with regard to the McCarthy article are moot considering the fact that the reference is not prior art given the filing date of the application as well as the fact that the article only shows that indomethacin and ibuprofen were ineffective for reducing cachexia. The very fact that the authors experimented with prostaglandin inhibitors for the treatment of cachexia based on previous findings of tumor induced anorexia and PG inhibitors only supports the examiner's position that there was a reasonable expectation to use PG inhibitors in the treatment of cachexia in the prior art at the time of filing.

Applicant is asserting that even though the prior art recognizes the compounds of the invention as prostaglandin inhibitors and teaches that inhibitors of prostaglandins have been shown to be beneficial as one of the factors for decreasing cachexia in vivo, there exists no reasonable expectation that the compounds would be useful in the treatment of cachexia. This assertion is not convincing based on the teachings of the prior art and the rejection is therefore maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Howard Owens whose telephone number is (703) 306-4538. The examiner can normally be reached on Tuesday-Friday 9 a.m.-6:30 p.m. (EST).

If attempts to reach the examiner by telephone are unsuccessful, Mr. Gary Geist (703) 308-1701, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.



GARY GEIST
SUPERVISORY PATENT EXAMINER
TECH CENTER 1600